General

Guideline Title

Immunizations.

Bibliographic Source(s)

Nordin J, Anderson R, Anderson R, Garvis M, Kephart K, Myers C, Ottis B, Rall S, Retzer K, Starr A, Institute for Clinical Systems Improvement (ICSI). Immunizations. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2012 Mar. 81 p. [84 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Immunizations. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2011 Mar. 70 p. [72 references]

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): In January 2013 the ICSI Immunization Work Group created new recommendations for the pneumococcal vaccination. The updated recommendations are included in Annotation #20 below. In May 2014 the ICSI Immunization Work Group modified the recommendations for *haemophilus influenza* b Conjugate (HIB) vaccine and the meningococcal vaccine. The modified recommendations are included in Annotations #10 and #19 below, respectively. The Work Group has also included supplemental information about the pending human papillomavirus 9 (HPV9) vaccine in Annotation #19 below

For a description of what has changed since the previous version of this guidance, refer to Summary of Changes Report -- March 2012 . In addition, ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. This document is in transition to the GRADE methodology. Transition steps incorporating GRADE methodology for this document include the following:

- Priority placed upon available Systematic Reviews in literature searches
- All existing Class A (randomized controlled trials [RCTs]) studies have been considered as high quality evidence unless specified differently by a work group member.
- All existing Class B, C and D studies have been considered as low quality evidence unless specified differently by a work group member.
- All existing Class M and R studies are identified by study design versus assigning a quality of evidence (see Crosswalk between ICSI Evidence Grading System and GRADE below in the "Definitions" section).
- All new literature considered by the work group for this revision has been assessed using GRADE methodology.

The recommendations for immunizations are presented in the form an algorithm and immunization schedules with a total of 23 components accompanied by detailed annotations. Immunization schedules and an algorithm for Immunization Administration are provided in the original guideline document at the ICSI Web site. Clinical highlights and selected annotations (numbered to correspond with the algorithm) are provided below.

See the "Qualifying Statements" field for specific information related to vaccine shortages; persons vaccinated outside the United States, including internationally adopted children; and combination vaccines.

Class of evidence (Low Quality, Moderate Quality, High Quality, Meta-analysis, Systematic Review, Decision Analysis, Cost-Effectiveness Analysis, Guideline, and Reference) definitions are provided at the end of the "Major Recommendations" field.

Clinical Highlights

- Utilize all clinical encounters as opportunities to assess a patient's immunization status. (*Annotations #1, 2, 3; Aim #1 - see the original guideline document*)
- Administer at each clinical encounter all immunizations that are due or overdue unless true contraindications exist. (*Annotations #2, 3, 4; Aim #1 - see the original guideline document*)
- Educate patients (parents, if applicable) regarding the importance of infant, childhood, adolescent, and adult immunizations, the recommended schedule and the need to maintain a personal record of immunizations and childhood diseases. (*Annotation #3; Aim #2 - see the original guideline document*)
- Document reasons for not administering immunizations that are clinically indicated, and flag the record for a recall appointment. (*Annotations #4, 8*)
- Document the future plan for administering immunizations. (*Annotation #7*)
- Report immunizations to immunization registries and Vaccine Adverse Event Reporting System (VAERS). (*Annotation #6*)
- Provide vaccine information sheets. (*Annotation #3 - see the original guideline document*)

Immunization Schedules

See the original guideline document for the following immunization schedules:

- Recommended and Minimum Ages and Intervals Between Doses of Routinely Recommended Vaccines
- Vaccines Routinely Administered in the United States
- Recommended Immunization Schedule for Persons Aged 0 Through 6 Years--United States, 2012
- Recommended Immunization Schedule for Persons Aged 7 Through 18 Years--United States, 2012
- Catch-up Immunization Schedule for Persons Aged 4 Months Through 18 Years Who Start Late or Who Are More Than 1 Month Behind--United States, 2012
- Recommended Adult Immunization Schedule--United States, 2012
- Vaccines That Might Be Indicated for Adults Based on Medical and Other Indications
- Catch-Up Schedule and Minimum Intervals for Adults

Immunization Administration Algorithm Annotations

1. Review and Update Immunization Status
   Recommendation:

   - Immunization status should be reviewed for all patients at each office visit.

   Ask patient if they have received vaccinations elsewhere and/or review immunizations information in state or local immunization information systems (i.e., immunization registries).

   Providers should only accept written, dated records as evidence of vaccination. With the exception of influenza vaccine and pneumococcal polysaccharide vaccine (PPSV), self-reported doses of vaccine without written documentation should not be accepted. Although vaccinations should not be postponed if records cannot be found, an attempt to locate missing records should be made by contacting previous health care providers, reviewing state or local immunization information systems (IIS), and searching for a personally held record. If records cannot be located, these persons should be considered susceptible and should be started on the age-appropriate vaccination schedule. Serologic testing for immunity is an alternative to vaccination for certain antigens (e.g., measles, rubella, hepatitis A, and tetanus).

   Document historical vaccines in patient's medical record. At a minimum, include vaccine and date administered.

   [Guideline]

2. Are Immunizations Needed Today?
   Compare patient's immunization history to current recommended immunization schedules to identify needed immunizations (see schedules in the original guideline document).

   Vaccine recommendations are determined after extensive studies in large clinical trials. They include studies on how vaccine recipients respond to multiple vaccines given simultaneously. The overall aim is to provide early protection for infants and children against vaccine-preventable diseases that could endanger their health and life. No scientific evidence exists to support that delaying vaccinations or separating them into individual antigens is beneficial for children. Rather, this practice prolongs susceptibility to disease, which could result in a greater likelihood of the child becoming sick with a serious or life-threatening disease. There could also be added expense (e.g., multiple office visits), additional time off from work for parents, and increased likelihood that the child will fail to get all necessary vaccinations.

   For more information refer to the Childhood Immunization Schedule: Why Is It Like That? (AAP)
   http://www.vaccinateyourbaby.org/pdfs/Vaccine_schedule.pdf

   Patients should receive all routinely recommended immunizations.

   Patients with medical risk factors, lifestyle risk factors, or certain occupations may need additional vaccines.

   If the minimum interval between doses in a series has not been met, defer vaccine and schedule appointment when dose can be administered (see Catch-Up Immunization Schedule for Persons Aged 4 Months Through 18 Years Who Start Late or Are More Than 1 Month Behind [CDC] or Catch-Up Schedule and Minimum Intervals for Adults [Minnesota Department of Health (MDH)]) in the original guideline document). It is not necessary to restart the series if there has been a delay between doses of vaccine in a series.

   [Guideline]

   Responding to Vaccine-Hesitant Parents

   Most parents believe in the benefits of immunization for their children. However, health care providers may encounter parents who question the need for, or safety of, childhood vaccines. Such parents may choose to delay or forgo immunizing their children with some or all of the recommended vaccines. To assist parents in making fully informed immunization decisions, providers should try to understand differing views of vaccine risks and benefits, and be prepared to respond effectively to concerns and questions. There are many tools available to assist with this discussion such as:

   - Talking with Parents about Vaccines for Infants: http://www.cdc.gov/vaccines/spec-grps/hcp/downloads/talk-infants-bw-office.pdf
   - Clear Answers & Smart Advice About Your Baby's Shots, By Ari Brown, MD, FAAP: http://www.immunize.org/catg.d/p2068.pdf
   - Immunization Action Coalition form "Decision to Not Vaccinate My Child." Intended to be reviewed and signed by the parent, the form includes information about how an unvaccinated child might get seriously ill or could spread disease to another person. A second page includes background information and reference material for health care professionals:
     http://www.immunize.org/express/issue963.asp#n4

3. Can Needed Immunizations Be Given Today? (Educate, Reassure and Screen for Contraindications)
   Educate Patient, Parent/Guardian about Vaccine

   Recommendations:

   - Providers should discuss with the patient the benefits of vaccines, the diseases that the vaccines prevent and any known risks from vaccines.
   - Providers should follow only medically accepted contraindications.

   Providers should discuss with the patient the benefits of vaccines, the diseases that the vaccines prevent, and any known risks from vaccines. These issues should be discussed in the patient's native language, whenever possible. Printed materials, accurately translated into the patient's language, should be provided. For most commonly used vaccines, the U.S. federal government has developed Vaccine Information Statements (VISs) to give to potential vaccine recipients. For vaccines covered by the National Childhood Vaccine Injury Act, including those vaccines used in children, these forms are required. These statements are available in English and other languages. Where a form is available for vaccines not covered by the National Childhood Vaccine Injury Act, it should be used. Ample time should be allotted with patients, parents/guardians to review written materials and address questions and concerns. Patients, parents/guardians should be encouraged to take responsibility for ensuring that the patient is fully vaccinated. Providers should encourage patients, parents/guardians to

inform the health care professional of adverse events after the vaccine is administered and explain how to obtain medical care, if necessary. Information and assistance can be obtained by calling the CDC-INFO Contact Center (1-800-232-4636) or on the Internet at http://www.cdc.gov/vaccines.

[Guideline]

Assess Patient for Contraindications or Precautions

Providers should follow only medically accepted contraindications. Failure to differentiate between valid and invalid contraindications often results in the needless deferral of indicated vaccinations. Some of the most common invalid contraindications are mild illnesses, conditions related to pregnancy and breast-feeding, allergies that are not anaphylactic in nature, and certain aspects of the patient's family history. Providers should ask about any condition or circumstance that might indicate that a vaccination should be withheld or delayed. Providers should also inquire about previous adverse events temporally associated with any vaccination *[Guideline]*.

Health care professionals should refer to the Guide to Contraindications to Vaccinations published by the CDC at http://www.cdc.gov/vaccines/recs/vac-admin/contraindications-vacc.htm.

Simultaneously Administer All Doses of Vaccine for Which the Patient Is Eligible

Administering vaccines simultaneously (at the same visit), in accordance with recommendations from the Advisory Committee on Immunization Practices, the American Academy of Pediatrics and the American Academy of Family Physicians is safe, effective and indicated. Although the immunization schedule provides age flexibility for administering certain vaccine doses, simultaneous administration decreases the number of visits needed and the potential for missed doses, and it enables earlier protection. When indicated vaccines are not simultaneously administered, arrangements should be made for the patient's earliest return to receive the needed vaccination(s). See Annotation #2, "Are Immunizations Needed Today?" above for additional information regarding the recommended immunization schedule.

- Live virus vaccines (measles, mumps, rubella [MMR], MMR and varicella [MMRV], varicella, herpes zoster, and live attenuated influenza vaccine) not given simultaneously, should be separated by at least four weeks.
- Combination immunizations offer the benefit of a single injection and may improve compliance and reduce morbidity *[Guideline]*. See the "Vaccines Routinely Administered in the United States" section in the original guideline document for further information.

4. Document Contraindications, Deferrals, or Refusals
If a vaccine is contraindicated or deferred, the provider should document the reason and flag the record for future visits.

   Patients, Parents/Guardians Who Refuse Immunizations

   Document the discussion and keep the form in the patient's medical record. Revisit the immunization discussion at each subsequent appointment, and carefully document the discussion, including the benefits to each immunization and the risk of not being age-appropriately immunized. For unimmunized or partially immunized children, some providers may want to flag the chart to be reminded to revisit the immunization discussion, as well as to alert the provider about missed immunizations when considering the evaluation of future illness, especially young children with fever of unknown origin.

   State Immunization Laws

   As a core component of public health practice in the United States, vaccination programs are supported by state legal requirements. Each state has school vaccination laws that require children of appropriate age to be vaccinated for several communicable diseases. In addition to medical exemptions offered in each state, 48 states allow for religious exemptions, and 21 states allow personal belief exemptions for day care and school. For additional information on state requirements and exemptions, see Immunization Action Coalition at http://www.immunize.org/laws or CDC at http://www.cdc.gov/vaccines/vac-gen/laws/default.htm.

   [Guideline]

5. Administer Vaccines
Immunizations should be administered by properly trained individuals. Health care professionals or others who administer vaccinations should be knowledgeable and receive continuing education in vaccine storage and handling; the recommended vaccine schedule, contraindications, and administration techniques; treatment and reporting of adverse events; vaccine benefit and risk communication; and vaccination record maintenance and accessibility. The CDC sponsors distance-based training opportunities for health care professionals. Information about training is available at http://www.cdc.gov/vaccines/ed/default.htm.

[Guideline]

6. Document Vaccines Given and Report Dose to Registry
   Accurate record keeping helps ensure that needed vaccinations are administered and unnecessary vaccinations are not administered. The medical record at the primary care provider's office, clinic or worksite should include all vaccinations received (such as those received at a specialist's office or in another health care setting). When a health care professional who does not routinely care for a patient vaccinates that patient, the patient's primary care provider should be informed.

   [Guideline]

   Document Vaccine(s) Given

   Providers of routine childhood immunizations are required by federal law (42 U.S. Code 300aa-25) to record the vaccine, the date of administration, the vaccine manufacturer, lot number, the date the VIS was given to the patient, the publication date of the VIS, the signature and title of the person administering the vaccine, and the address where the vaccine was administered. It is recommended that providers of other vaccines also record this information. All information should be recorded in single summary form in the patient's record in order to allow easy retrieval of information. For additional information, see http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-instructions.pdf .

   [Guideline]

   Personal Immunization Record

   Health care professionals should ensure that each patient has a hand-held vaccination record that documents each vaccine received, including the date and the name of the health care professional who administered the vaccine. Health care professionals should encourage patients and/or parents/guardians to bring the patient's handheld record to each health care visit so that it can be updated.

   Report Vaccine(s) Given to Immunization Information Systems (i.e., Immunization Registries)

   All vaccinations administered should be reported to state or local immunization registries, where available, to ensure that each patient's vaccination history remains accurate and complete. Registries are useful for verifying the vaccination status of new patients, determining which vaccines are needed at a visit, printing official records, and providing reminders and recalls to parents/guardians and patients. For additional information, see Every Child by Two, at http://www.ecbt.org/registries .

   [Guideline]

   Report Vaccine Adverse Events

   Providers should document fully any adverse event in the medical record at the time of the event, or as soon as possible. Health care professionals should promptly report all clinically significant adverse events after vaccination to the Vaccine Adverse Event Reporting System (VAERS) even if the health care professional is not certain that the vaccine caused the event. Health care professionals should be aware that patients and parents/guardians may report to Vaccine Adverse Event Reporting System; if they choose to do so, they are encouraged to seek the help of their health care professional. Report forms and assistance are available by calling 1-800-822-7967 or on the Internet at http://vaers.hhs.gov/index .

   [Guideline]

7. Educate Parent/Patient. Arrange Follow-Up for Future Immunizations
   Discuss with the patient, parent/guardian when next vaccines are due (including vaccines that may have been deferred), and schedule appointment if possible. For additional information, refer to Annotation #3, "Can Needed Immunizations be Given Today? (Educate, Reassure and Screen for Contraindications)." Educate the patient and/or parent/guardian about vaccines.

   [Guideline]

8. Conduct Regular Assessments of Vaccination Coverage Rates. Develop Systems to Remind Patients and Providers When Vaccinations Are Due and to Recall Patients Who Are Overdue.
   Assessment of Vaccination Coverage Rates

   Assessments are most effective in improving vaccination coverage when they combine chart reviews to determine coverage with the provision of results to health care professionals and staff. Provider assessment can be performed by the staff in the practice or by other

organizations, including state and local health departments. Effective interventions that include assessment and provision of results may also incorporate incentives or compare performance to a goal or standard. This process is commonly referred to as AFIX (assessment, feedback, incentives and exchange of information). Coverage should be assessed annually so that reasons for low coverage in the practice, or in a subgroup of the patients served, can be identified and interventions implemented to address them.

[Guideline]

Reminder/Recall

Reminder/recall systems improve vaccination coverage. Patient reminder/recall interventions inform individuals that they are due (reminder) or overdue (recall) for specific vaccinations. Patient reminders/recalls can be mailed or communicated by telephone; an autodialer system can be used to expedite telephone reminders. Patients who might be at high risk for not complying with medical recommendations – for example, those who have missed previous appointments – should receive more intensive follow-up. Similarly, provider reminder/recall systems alert health care professionals when vaccines are due or overdue. Notices should be placed in patient charts or communicated to health care professionals by computer or other means. Immunization registries can facilitate automatic generation of reminder/recall notices.

Information about assessing vaccination coverage rates and reminder/recall systems is available through the CDC at http://www.cdc.gov/vaccines/programs/afix/default.html and through the American Academy of Pediatrics at http://www2.aap.org/immunization/pediatricians/pdf/ReminderRecall.pdf. Software to assist in conducting coverage rate assessments and feedback is available at http://www.cdc.gov/vaccines/programs/cocasa/default.html. Model reminder/recall templates are also available at http://www.ahcpr.gov/ppip/postcard.pdf.

[Guideline]

Immunization Schedule Annotations

9. Diphtheria and Tetanus Toxoids and Acellular Pertussis (DTaP/Td/Tdap) Vaccine
   DTaP

   Children up to Age 7

   It is recommended that children receive a series of five doses of vaccine against diphtheria, tetanus and pertussis administered at ages 2, 4, 6 and 15-18 months and the fifth dose at age 4-6 years. The fourth dose of DTaP may be administered as early as age 12 months, provided six months have elapsed since the third dose and the child is unlikely to return at 15-18 months.

   DTaP can be given in single syringe combination with Hib (*Haemophilus influenzae* B) and IPV (inactivated polio virus) *[Guideline]*, *[High Quality Evidence]*, *[Low Quality Evidence]*, or in combination in a single syringe with hepatitis B vaccine and IPV *[High Quality Evidence]*. Whether given alone or in combination, whenever feasible use the same brand of DTaP throughout the five-dose series to minimize injection site swelling.

   Children with neurologic disorders may have the DTaP vaccine deferred on an individual basis for such reasons as progressive neurologic disorder, children with poorly controlled seizures, and neurologic conditions predisposing to seizures or neurologic deterioration (e.g., tuberous sclerosis). DTaP use should be reconsidered at each visit and initiated if the clinical condition is stable or controlled. If DTaP has not been initiated by one year of age, DT series should be started. A personal or family history of stable convulsive disorder is not a contraindication to DTaP vaccination. Counseling of the family should be undertaken prior to administration.

   Preterm infants in stable medical condition should be immunized with DTaP at two months of chronological age *[Moderate Quality Evidence]*.

   Td/Tdap

   Children Ages 7 through 10

   A single dose of tetanus, diphtheria toxoids and acellular pertussis vaccine (Tdap) should be given to children aged 7 through 10 years who are not fully vaccinated against pertussis (five doses of DTaP or four doses of DTaP if the fourth dose was given on or after the fourth birthday), provided they have no contraindication to pertussis vaccine *[Guideline]*.

   Children aged 7 through 10 years who were never vaccinated against tetanus, diphtheria or pertussis, or who have unknown vaccination status, should receive a series of three vaccinations containing tetanus and diphtheria toxoids with Tdap as the first of these three doses

[Guideline].

Adolescents and Adults

A single dose of Tdap should be given routinely to adolescents (target age 11-12) who completed the recommended childhood diphtheria and tetanus toxoids, pertussis/diphtheria and tetanus toxoids, and acellular pertussis (DTP/DTaP) vaccination series. Tdap can be given regardless of the time elapsed since the last vaccine containing tetanus toxoid or diphtheria toxoid *[Guideline]*.

Pertussis appears to be endemic in middle and high schools *[Low Quality Evidence]*. Although mortality is very low in patients ages 11 to 65 years, pertussis causes substantial morbidity in this age as well as transmission to incompletely immunized infants *[Guideline]*. Thus, the availability of a safe Tdap for adolescents and adults means it should be routinely given to these age groups. In most situations, Tdap will substitute for tetanus and diphtheria (Td). Immunization should be provided to those who may expose infants less than six months of age, because these infants are the most vulnerable to the disease. This cocoon strategy will maximize the effectiveness of the vaccine in reducing disease *[Guideline]*.

Given the epidemiology of the disease, the most important groups to immunize with Tdap are listed below:

- All health care workers since they are at risk of transmitting pertussis to infants, adolescents, parents, grandparents or care providers of infants *[Reference]*
- Middle and high school age patients
- Others with high exposure to middle and high school age patients (teachers, health care workers, etc.)
- Those who might expose infants less than 6 months of age to pertussis (pregnant women, postpartum women, new parents, siblings of infants, day care workers, health care professionals, etc.)

Primary Immunization of Adults 18 and Older

All adults should have completed a primary Td series. A complete series includes two doses given four weeks apart and a third dose given 6-12 months after the second dose. Tdap should be used as the first dose (Tdap is not tested or licensed as a repeated immunization) *[Guideline]*.

Repeat Immunization of Adults 18 and Older

For all adults, a booster dose of Td is recommended every 10 years. Those who have not had a one-time dose of Tdap, or if status is unknown, the next booster dose should be Tdap. Adults 65 years and older who haven't received Tdap SHOULD be vaccinated *[Guideline]*.

For patients presenting with severe or complicated trauma wounds, an additional dose is recommended if Td has not been administered within the preceding 5 years. If available, Tdap should be given. If the initial tetanus series is incomplete, the tetanus diphtheria status is unknown or patient is human immunodeficiency virus (HIV)-positive, tetanus immune globulin should be given in addition to starting the series *[Reference]*.

Pregnancy and Postpartum Period

Pregnant women who were not vaccinated previously with Tdap should receive Tdap during pregnancy, preferably during the third or late second trimester (after 20 weeks gestation). If not administered during pregnancy, Tdap should be administered immediately postpartum.

In addition, parents of infants, siblings of newborns, day care providers and others caring for the newborn should all be offered Tdap.

Tdap vaccination of parents and household contacts of premature infants has been advocated *[Reference]*. Premature and low-birth-weight infants are at increased risk for severe and complicated pertussis.

[Guideline]

10. *Haemophilus influenzae b* Conjugate (Hib) Vaccine
See the original guideline document for information about the available *Haemophilus influenza b* conjugate (Hib) vaccines, including trade name, carrier, and usual schedule.

This information is current as of February 2014. See prescribing information for complete details of the products' licensure http://www.immunize.org/packageinserts. For the most up-to-date information about specific recommendation, see Child, Adolescent, and Catch-Up Schedules.

11. Hepatitis A (Hep A) Vaccine
    Routine

    Initiation of hepatitis A vaccine is recommended for all children between 12 and 23 months.

    Hepatitis A requires two doses administered at least 6 months apart. It is not necessary to restart the series if the interval between doses is longer than recommended. Those 24 months and older who have started the series should complete it. Otherwise, those 24 months and older who have not started the series, should be considered for vaccination if they are at increased risk. It is also recommended for those who live in areas where vaccination programs target older children, or who are at increased risk for infection, or for whom immunity against hepatitis A is desired. States and regions that have risk-based hepatitis A vaccination programs for children 2 to 18 years of age should continue these programs *[Reference]*.

    Increased Risk

    Hepatitis A vaccine is recommended for persons 12 months and older who are at increased risk for the disease, including:

    - Persons traveling to or working in countries that have high or intermediate endemicity of infection
    - Men who have sex with men
    - Users of injectable or non-injectable illegal drugs
    - Persons who have occupational risk for infection (e.g., people who work with hepatitis A-infected persons, people who use hepatitis A in a research laboratory setting). No other occupational group has demonstrated to be at increased risk.
    - Persons with clotting-factor disorders who require clotting-factor concentrates, especially solvent-detergent treated preparations
    - Persons with chronic liver disease
    - Military personnel
    - Unvaccinated persons who anticipate close personal contact with an international adoptee during the first 60 days after arrival in the United States from a country with high or intermediate endemicity.

12. Hepatitis B (Hep B) Vaccine
    The ICSI work group recommends universal vaccination for those less than 40 years of age and for those over age 40 at high risk.

    High Risk

    Those at high risk for exposure include the following:

    - Sex partners of hepatitis B surface antigen (HBsAg) positive persons
    - Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than one sex partner during the previous 6 months)
    - Persons seeking evaluation or treatment for a sexually transmitted disease (STD)
    - Current or recent injection-drug users
    - Men who have sex with men
    - Health care personnel and public-safety workers with reasonably anticipated risk for exposure to blood or other blood-contaminated body fluids
    - Persons with end-stage renal disease, including predialysis, hemodialysis, peritoneal dialysis, and home dialysis patients
    - Persons with HIV infection
    - Persons with chronic liver disease
    - Household contacts of HBsAg-positive persons
    - Residents and staff of facilities for developmentally disabled persons
    - International travelers to countries with high or intermediate prevalence of chronic hepatitis B infection
    - Hepatitis B vaccine should be administered to unvaccinated adults with diabetes who are <60 years of age
    - Hepatitis B vaccine may be administered to unvaccinated adults with diabetes who are ≥60 years of age

    Hepatitis B vaccination is recommended for all adults in the following settings:

    - Sexually transmitted disease (STD) treatment facilities
    - HIV testing and treatment facilities
    - Facilities providing drug-abuse treatment and prevention services
    - Health care settings targeting services to injection-drug users or men who have sex with men
    - Correctional facilities
    - End-stage renal disease programs and facilities for chronic hemodialysis patients

- Institutions and non-residential day care facilities for persons with developmental disabilities

[Reference]

Schedule and Dosing Considerations

The recommended amount of hepatitis B vaccine varies by age and manufacturer and schedule. The package insert information should be consulted for details.

All infants and children not previously immunized should receive three doses of hepatitis B vaccine. Four doses may be given if the first dose is given at birth. The first and second doses should be given a minimum of 4 weeks apart. The second and third doses are to be given a minimum of 8 weeks apart. The first and third doses are to be given at least 16 weeks apart. The last (third or fourth) dose of Hepatitis B vaccine should not be given before 6 months of age.

Authorities recommend that whenever possible, the routine series of hepatitis B vaccination should begin at the infant's birth *[Reference]*.

There is an accelerated or alternate schedule of 0, 1, 2 and 12 months for hepatitis B vaccine (Engerix B®). This vaccine is available for use in special circumstances where faster and prolonged sero-protective levels are desired, such as neonates born of hepatitis B-infected mothers, recent exposure to the virus, or travelers to high-risk areas leaving in less than three months.

See the original guideline document for special considerations with regard to infants born to hepatitis B-positive mothers, adolescents, and recipients of hemodialysis and other immunosuppressed adults, as well as the role of postimmunization testing and the management of postimmunization serology test results.

13. Hepatitis A (Hep A) and Hepatitis B (Hep B) Combination Vaccine
    Twinrix® contains both hepatitis A vaccine and hepatitis B vaccine, and is licensed for adults 18 years and older. Twinrix® requires three doses. The second dose should be given 1 month after the first, and the third dose 6 months after the first dose and 5 months after the second dose.

    A dose of Twinrix® contains less hepatitis A viral antigen than a dose of single antigen adult hepatitis A vaccine. To complete the hepatitis A vaccine series, an adult patient must receive three doses of Twinrix® or two adult doses of single-antigen hepatitis A vaccine. It is not recommended to administer two doses of Twinrix® and one dose of single-antigen hepatitis B vaccine to complete the hepatitis A and B series *[Reference]*.

    In 2007, the Food and Drug Administration approved the hyperaccelerated 0, 7-, 21- to 30-day and 12-month booster schedule for Twinrix® for people needing protection in a short period of time (i.e., travelers). Seroprotection against hepatitis A and hepatitis B from the accelerated Twinrix® schedule was comparable to monovalent hepatitis A vaccine and hepatitis B vaccine schedules *[Guideline]*.

14. Herpes Zoster/Shingles Vaccine
    Zoster vaccine is recommended for all persons aged 60 years or older who have no contraindications, including persons who report a previous episode of zoster or who have chronic medical conditions. The vaccine should be offered at the patient's first clinical encounter with his or her health care provider. It is administered as a single 0.65 mL dose subcutaneously in the deltoid region of the arm. A booster dose is not licensed for the vaccine.

    The Zostavax® Efficacy & Safety Trial ("ZEST") was recently completed in persons ages 50 to 59. In March 2011, the Food and Drug Administration extended the indications for zoster vaccine to adults ages 50 to 59. However, the work group concurs with the recent Advisory Committee on Immunization Practices (ACIP) recommendation and does not propose revision of existing recommendations regarding zoster vaccine *[Guideline]*. The rationale for this conclusion is that there is insufficient evidence regarding duration of vaccine protection to vaccinate well before the peak of zoster incidence.

    Zoster vaccination is not indicated to treat acute zoster, to prevent persons with acute zoster from developing postherpetic neuralgia, or to treat ongoing postherpetic neuralgia. Before administration of zoster vaccine, patients do not need to be asked about their history of varicella (chicken pox) or to have serologic testing conducted to determine varicella immunity *[Reference]*.

    There is a recently published study that looks at the antibody response that occurred with the concomitant administration of zoster vaccine (VZV) and pneumococcal vaccine (PPV 23) in adults >60 years old *[High Quality Evidence]*. The concomitant administration did not affect the immunogenic response to PPV 23 in those tested and both vaccine groups achieved acceptable levels of antibody titers. However, the zoster vaccine antibody response was lower in those individuals who received concomitant vaccines as compared to those who received the vaccine alone. The study recommends that these vaccines not be administered together as lower immune responses correlate with lower efficacy. It is the opinion of the work group that efforts should be made to administer these vaccines separately unless

there is doubt about an individual's ability to return in a timely manner for further vaccines. In that case, given the data that indicates that acceptable immunity is reached, it would be reasonable to administer both vaccines at a single visit.

Due to lack of data, zoster vaccination is not recommended for persons of any age who have received varicella vaccine. However, health care providers do not need to inquire about varicella vaccination or disease history before administering zoster vaccine because virtually all persons currently or soon to be in the recommended age group have not received varicella vaccine *[Reference]*. Adult immigrants coming from tropical climates should have a varicella titer drawn, and if it suggests previous varicella infection, patients ages 60 and older should be offered ZOSTAVAX®, and those without a positive titer should receive two doses of the varicella vaccine *[Reference]*.

See the "Contraindications" field for information about who should not receive the zoster vaccine.

15. Human Papillomavirus (HPV) Vaccine
The doses may be given on a 0, 2- and 6-month schedule. Minimum intervals between doses are as follows: 4 weeks between the first and second dose, 12 weeks between the second and third dose, and 24 weeks between the first and third dose. The prelicensure trials were very relaxed about schedule, and all intervals worked well. Thus, it is never necessary to restart the series. It is acceptable to administer doses beyond 27 years of age if the series is started prior to 27 years.

Females

Two human papillomavirus vaccines are licensed: a quadrivalent vaccine, HPV4 (Gardasil), for the prevention of cervical, vaginal, vulvar, anal, and orofacial cancers and genital warts; and a bivalent vaccine, HPV2 (Cervarix), for the prevention of cervical, vaginal, vulvar, and orofacial cancers in females. They are licensed for ages 9 through 26, and the Advisory Committee on Immunization Practices recommends routine use of the vaccine for all 11- to 12-year-old females, and catch-up use of the vaccine for females ages 12 through 26 *[Reference]*. The strains included in HPV4 (Gardasil) are 6, 11, 16 and 18. Strains 6 and 11 (present only in HPV4) account for 90% of venereal warts. Strains 16 and 18 are present in both HPV4 and HPV2 and account for 70% of oncogenic infections *[Guideline]*.

If pregnancy occurs before the series is completed, further vaccination should occur after the pregnancy is over.

Currently an HPV9 (9-valent HPV) vaccine is being investigated by the FDA and anticipated review of recommendations by ACIP in early 2015. The strains included in the new HPV9 are 6, 7, 16, 18 (in current vaccine) plus 31, 33, 45, 52, 58. Strains 16 and 18 account for 50% of High-grade cervical lesions (CIN2) and 25% are attributable to the additional five types in HPV9. Strains 16 and 18 account for 62% of associated cancers and 11% are attributable to the additional five types in HPV 9. This vaccine is currently being studied in female populations, and may expand to the male population.

Males

The ACIP has recently recommended the routine vaccination of boys ages 11 or 12 with three doses of quadrivalent vaccine, HPV4 (Gardasil), to protect them against HPV. The vaccine received a permissive recommendation in 2009, but it was not part of the routine ACIP recommended vaccines. On further review, it was felt that this new recommendation was justified due to increasing rates of anal cancer and head and neck cancers, as well as the direct benefit of preventing genital warts in males. It is also postulated that the vaccine will reduce male-to-female transmission of HPV due to disappointing rates of female HPV vaccinations.

Current guidelines are as follows: routine vaccination of males ages 11 to 12 years with 3 doses of HPV4. The vaccination series can be started beginning at age 9. Males ages 13 to 21 years who had not already received the HPV4 vaccine should also be vaccinated. Males ages 22 through 26 years of age may be vaccinated.

[Guideline]

16. Inactivated Poliovirus (IPV) Vaccine
Oral poliovirus vaccine (OPV) is no longer available in the United States but is used in increasingly successful eradication efforts worldwide *[Guideline]*.

Most adults living in the United States are immune as a result of vaccination received as children. Furthermore, adults in the United States, in general, have little risk of exposure to wild-type poliovirus. Vaccination is recommended for non-immune adults who are at a greater risk of exposure to wild-type polioviruses, including the following:

- Travelers to areas or countries where polio is or may be epidemic or endemic
- Members of communities or specific population groups with polio
- Laboratory workers handling specimens that may contain polio viruses

- Health care professionals in close contact with patients who may be excreting wild-type polio viruses

Fully immunized adults with high risk of exposure to wild-type virus may receive one dose of inactivated polio vaccine.

Incompletely immunized adults may receive the remaining doses of inactive poliovirus vaccine regardless of the length of time since the past doses or the forms of the vaccine.

Unimmunized adults should undergo primary immunization with the inactivated poliovirus vaccine. This is recommended over a minimum of 7 months. The second dose should be given 4 to 8 weeks after the first, followed by a third dose given 6 to 12 months after the second dose.

See the original guideline document for considerations for the unimmunized adults.

17. Influenza Vaccine

Indications

Influenza vaccination of all people ages 6 months and older is recommended annually, through the entire influenza season *[High Quality Evidence]* including women who are pregnant or will be pregnant during the influenza season. Limited safety data exist for the first trimester; however, the ACIP suggests that vaccination may occur in any trimester and should be completed with inactivated injectable influenza vaccine (TIV).

Those at risk for serious complications from influenza include those who:

- Have chronic heart disease
- Have chronic lung disease (including asthma and reactive airway disease)
- Smoke tobacco products
- Have diabetes
- Have kidney failure
- Have illnesses that weaken the immune system
- Are taking medications that weaken the immune system
- Are children or adolescents receiving aspirin therapy
- Are pregnant
- Care for young children
- Are children age 6 months to 2 years (who are too young to receive live attenuated influenza vaccine [LAIV])

Children age 6 months through 8 years receiving influenza vaccine for the first time should receive two doses administered at least one month apart. For the 2011-12 influenza season, a second dose of influenza vaccine was recommended for children age 6 months through 8 years who did not receive influenza vaccine during the 2010-11 season regardless of the number of doses of influenza vaccine received in prior years. For the 2012-13 season, follow dosing guidelines in the 2012 ACIP influenza vaccine recommendations.

[Guideline]

Contraindications

Contraindications include severe allergic reaction to any component of the vaccine, including egg protein, or after previous dose of any influenza vaccine.

Although data are limited, the established benefits of influenza vaccination for the majority of persons who have a history of Guillain-Barré syndrome (GBS) and who are at high risk for severe complications from influenza justify yearly vaccination. It is prudent to avoid vaccinating persons who are not at high risk for severe influenza complications but who are known to have developed Guillain-Barré syndrome within 6 weeks after receiving a previous influenza vaccination.

[Guideline], *[Reference]*

Recommendations Regarding Persons with Egg Allergy

Persons who have experienced only hives following exposure to egg should receive influenza vaccine with the following additional measures:

- Because studies published to date involved use of trivalent inactivated influenza vaccine (TIV) rather than LAIV should be used.
- Vaccine should be administered by a health care provider who is familiar with the potential manifestations of egg allergy.
- Vaccine recipients should be observed for at least 30 minutes for signs of a reaction following administration of each vaccine dose.

Other measures, such as dividing and administering the vaccine by a two-step approach and skin testing with vaccine, are not necessary.

[Guideline]

LAIV

Persons should NOT receive live attenuated influenza vaccine if they:

- Have chronic heart disease (except hypertension)
- Have chronic lung disease (including asthma and reactive airway disease)
- Have diabetes
- Have kidney failure
- Have illnesses that weaken the immune system
- Are taking medications that weaken the immune system
- Are children or adolescents receiving aspirin therapy
- Are pregnant
- Have a history of allergy to eggs (or any vaccine component)

Live attenuated influenza vaccine is a good alternative for healthy health care workers up to 50 years of age. Only those caring for patients in protective environments, such as bone marrow transplant wards, should not receive live attenuated influenza vaccine. For persons directly caring for a person who is severely immunocompromised and in protective isolation, inactivated vaccine is preferred over live attenuated vaccine.

Live attenuated influenza vaccine can be administered simultaneously with other inactivated vaccines or live vaccines. Live attenuated influenza vaccine may be given to persons with minor illnesses (e.g., diarrhea or mild upper respiratory tract infection with or without fever). However, if nasal congestion is present, that might limit delivery of the vaccine to the nasal lining. Consider delaying the vaccination until nasal congestion subsides. Health care workers should wear disposable gloves when administering live attenuated influenza vaccine.

Side effects of live attenuated influenza vaccine can include runny nose, headache, vomiting, muscle aches, sore throat, cough and fever (though fever is not a common side effect in adults receiving live attenuated influenza vaccine).

The effect on safety and efficacy of live attenuated influenza vaccine co-administration with influenza antiviral medications has not been studied. However, because influenza antivirals reduce replication of influenza viruses, live attenuated influenza vaccine should not be administered within 48 hours after cessation of influenza antiviral therapy, and influenza antiviral medications should not be administered for 2 weeks after receipt of live attenuated influenza vaccine.

[Guideline], *[Reference]*

TIV

Forms of TIV

- Standard dose killed vaccine for intramuscular (IM) use. 0.5 ml in patients aged three years and older and 0.25 ml in patients aged 6 through 35 months.
- Intradermal administration with a special device. 0.1 ml intradermally for patients aged 18-64 years.
- High dose for use in patients age 65 and older. This vaccine contains four times as much antigen. The dose is 0.5 cc IM.

The immunogenicity of the intradermal vaccine is similar to the intramuscular vaccine. The high-dose vaccine does produce better antibodies in the elderly and somewhat more side effects. It is not known yet whether this vaccine is more effective in this age group.

See the original guideline document for additional information.

18. Measles, Mumps and Rubella/Measles, Mumps, Rubella and Varicella (MMR/MMRV) Vaccine
The first dose of measles, mumps and rubella (MMR) immunization is recommended between 12 to 15 months of age (minimum age 12 months).

    Recommended timing for the second immunization is at 4-6 years, but it is acceptable to give as soon as 4 weeks after the first.

    A personal or family history of convulsive disorders is not a contraindication to measles vaccination. There is good epidemiologic evidence that autism is not caused by measles-containing vaccine *[Reference]*, *[Low Quality Evidence]*.

    Adults lacking documentation of vaccination or evidence of disease who were born during or after 1957 should receive one dose of MMR. A second dose of MMR is recommended for adults who:

    - Were recently exposed to measles or in an outbreak setting
    - Were previously vaccinated with killed measles vaccine

- Were vaccinated with an unknown vaccine during 1963-1967
- Are students in postsecondary educational institutions
- Work in health care facilities
- Plan to travel internationally

[Reference]

Vaccination should not occur during pregnancy. Pregnant women who test negative for rubella immunity may need to receive another MMR vaccine postpartum. Based on community consensus, if the patient has documentation of two previous vaccinations, then a third vaccination should not be given. If two previous vaccinations have not been given, a dose of MMR should be given soon after delivery.

Combined measles, mumps, rubella and varicella vaccine (MMRV) may be provided for children 12 months through 12 years of age in lieu of separate injection of equivalent component vaccines.

For children younger than 13 years of age, the minimum interval between the first dose of varicella and a dose of MMRV (MMR and varicella in combination) is 12 weeks *[Guideline]*.

However, if the second dose of varicella vaccine was administered 28 days or more after the first dose, the second dose is considered valid and does not need to be repeated *[Reference]*.

As a general rule, the ACIP of the CDC has stated a preference for combination vaccines over separate injections of the same antigens. However, providers who are considering administering MMRV vaccine should discuss the benefits and risks of both vaccination options with the parents or caregivers. Unless the parent or caregiver expresses a preference for MMRV vaccine, the CDC recommends that MMR vaccine and varicella vaccine should be administered for the first dose. Given this information, the Immunizations work group consensus is that in most instances, separate administration of MMR and varicella vaccine is preferred at age 12 to 47 months, while at ages 4 to 6 years, the MMRV combination vaccine is preferred. *[Guideline]*

19. Meningococcal Vaccine
    Vaccination Recommendation

    MCV4-D/MCV4-CRM (Meningococcal conjugate A, C, W and Y) is recommended for all children aged 11 through 18 years:

    - A single dose of vaccine should be administered at age 11 or 12 (before entering 7th grade).
    - A booster dose should be administered at age 16 years.
    - A patient who receives their first dose at age 13 through 15 years should receive a booster dose at age 16 through 18 years.
    - A patient who receives their first dose after their 16th birthday does not need a booster dose unless they become at increased risk for the disease.
    - Patients aged 19 through 21 may receive one catch up dose if they are at an increased risk which may include: College student and living in residence halls, community outbreak or travel.

    There are four meningococcal vaccines currently Federal Drug Administration (FDA) approved for use in the United States. Three are quadrivalent vaccines effective against serogroups A, C, W135, and Y; polysaccharide vaccine Menomune®, and two conjugated vaccines – Menactra® and Menveo®. The fourth vaccine HibMenCY (MenHibrix) protects against serogroups C and Y and *Haemophilus influenza* type b and is recommended for children aged 2 through 18 months who are at increased risk for meningococcal disease (e.g., persistent complement component deficiencies, anatomic or functional asplenia, including sickle cell disease).

    Vaccination for Persons at Increased Risk

    Persons at increased risk for meningococcal disease are recommended for routine meningococcal vaccination. Vaccine product, number of doses and booster dose recommendations are based on age and risk factor and are shown in a table in the original guideline document.

    HIV-positive adolescents aged 11 through 18 years should receive a two-dose primary series of MCV4, at least eight weeks apart. Patients of other ages with human immunodeficiency virus are likely to be at increased risk for meningococcal disease and may elect vaccination.

    Colleges may elect to target their vaccination campaigns to all matriculating freshmen to facilitate vaccination of those at higher risk or those previously unvaccinated.

    The vaccines are safe and immunogenic and can be provided to nonfreshmen college students who want to reduce their risk for meningococcal disease and have not been previously vaccinated.

While the risk is relatively lower for adults aged 20 through 55 years who are not at increased risk for meningococcal disease, persons who wish to decrease their risk for meningococcal disease may elect to be vaccinated with the meningococcal conjugate vaccine.

Revaccination

The unconjugated meningococcal polysaccharide vaccine (MPSV4) is thought to give protection for at least two to three years but no more than five years. The meningococcal conjugated vaccine (MCV4) is thought to give protection for at least five years.

Persons with increased risk who were first vaccinated at less than four years of age with the unconjugated meningococcal polysaccharide vaccine should be considered for revaccination after two to three years with the conjugated vaccine.

20. Pneumococcal Vaccine (Updated January 2013)
The information on the 2012 Centers for Disease Control and Prevention immunization schedules are not current. The 2013 schedules, which are expected for release in February 2013, will include the information shown below.

Vaccine	Trade Name	Manufacturer
Pneumococcal conjugate (PCV13)	Prevnar13	Pfizer
Pneumococcal polysaccharide (PPSV23)	Pneumovax 23	Merck

PCV13

Routine vaccination of children:

- PCV13 is indicated for children age six weeks through 59 months and is administered at 2, 4, 6, and 12-15 months.
- Children age 14 through 59 months who have completed the series with PCV7 should receive a single supplemental dose of PCV13.

Vaccination of Persons with High-Risk Conditions

Persons with the high-risk conditions shown below are recommended to receive either PCV13 or PPSV23 or both vaccines.

Categories of High-Risk Conditions

1. Chronic heart disease, chronic lung disease, diabetes mellitus, adults ≥19 years: alcoholism, chronic liver disease (cirrhosis), asthma, cigarette smoking.
2. Candidate for or recipient of cochlear implant, cerebrospinal fluid leak.
3. Functional or anatomic asplenia: sickle cell disease, other hemaglobinopathy, congenital or acquired asplenia; immunocompromising conditions: congenital or acquired immunodeficiency (including B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease); HIV infection; chronic renal failure and nephrotic syndrome; leukemia, lymphoma, Hodgkin disease, generalized malignancy, solid organ transplant, multiple myeloma; iatrogenic immunosuppression (e.g., diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy).

Vaccination of Children Age 2 through 18 Years with High-Risk Conditions

Age	High-Risk Category	Recommendation
24 through 71 months	1, 2, and 3	1 dose PCV13 if 3 doses PCV were received previously, or 2 doses ≥8 weeks apart if <3 doses of PCV were received previously
6 through 18 years	2 and 3	1 dose PCV13 may be administered
2 through 18 years	1, 2, and 3	1 dose PPSV23 ≥8 weeks after last PCV dose
	3	PPSV23 booster ≥5 years after previous dose

Vaccination of Adults (Age 19 Years and Older) with High-Risk Conditions

Although PCV13 is licensed by the Food and Drug Administration (FDA) for persons age 50 years and older, the Advisory Committee on Immunization Practices (ACIP) recommends PCV13 for adults age 19 years and older with immunocompromising conditions. Greater immune response was demonstrated when PCV13 was administered before PPSV23.

High-Risk Category	PPSV23 Vaccine History	Recommendation		
1	0	PPSV23		PPSV23 at ≥65* Adults who received a dose of PPSV23 at age ≥65 years do not need another dose.
	1			
2	0	PCV13 1st, PPSV23 ≥8 weeks later		
	1	PCV13 ≥1 year after PPSV23		
3	0	PCV13 1st, PPSV23 ≥8 weeks later	PPSV23 #2*	
	1	PCV13 ≥1 year after PPSV23	PPSV #2 ≥8 weeks after PCV 13*	
	2	PCV13 ≥1 year after PPSV23		

*Additional doses of PPSV23 should be administered ≥5 years after previous PPSV23 dose.

[Guideline]

See the original guideline document for a flowchart for pneumococcal vaccine recommendations for adults age 19 years and older.

21. Rotavirus Vaccine

Trade Name	Abbreviation	Manufacturer	Dose	Schedule*	Notes
RotaTeq	RV5	Merck	2 mL, oral solution	2, 4, 6 months of age	Oral starting at 6 weeks of age or older, with subsequent doses at least 4 weeks apart. First dose by 14 weeks 6 days (before 15 weeks of age) and no doses after 8 months of age
Rotarix	RV1	GlaxoSmithKline	1 mL	2, 4 months of age	Oral starting at 6 weeks of age or older, with second dose at least 4 weeks after first dose. First dose by 14 weeks 6 days (before 15 weeks of age) and no doses after 8 months of age

*Recent ACIP recommendations for both rotavirus vaccines include changes for the maximum age for the first dose (14 weeks 6 days) and the maximum age for the final dose of the series (8 months 0 days) *[Guideline]*.

See the original guideline document for information on special considerations for rotavirus vaccine.

22. Varicella Vaccine
Catch-up Regimens*

Age	Schedule	Notes
12 months up to 13 years of age	12 months or older; 4-6 years of age	Minimum interval of 12 weeks; 2nd dose should occur before starting kindergarten or 1st grade
13 years and older	2 doses at least 28 days apart	

*Vaccination occurs when evidence of immunity does not exist.

A catch-up second dose of varicella vaccine is recommended for all children, adolescents and adults who received only one dose previously. The second dose of varicella vaccine improves individual protection and reduces the risk of school outbreaks. Providers should use every encounter to assess the need for a catch-up second dose of varicella vaccine, especially in those persons who received varicella vaccine between the ages of 12 months through 12 years at a time when only one dose had been recommended.

See the original guideline document for assessment of evidence of immunity and special indications for varicella vaccination.

23. Vaccinations for High-Risk Patients
    Vaccine Considerations for Special Case Patients

    Experience with vaccine use in immunocompromised persons and persons with chronic, underlying disease is limited. Each situation should be evaluated on an individual basis. Some general guidelines are presented in the original guideline document, which may help in making immunization decisions.

    See the original guideline document for information regarding vaccine considerations for the following special cases:

    - Prematurity
    - Patient receiving immunosuppressant medications
    - Immunodeficiencies
    - HIV-positive patients
    - Asplenics (patients with no spleen or dysfunctional spleen including sickle cell disease)

Definitions:

Following a review of several evidence rating and recommendation writing systems, Institute for Clinical System Improvement (ICSI) has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

Crosswalk between ICSI Evidence Grading System and GRADE

Design of Study Current ICSI System		ICSI GRADE System
Class A:	Randomized, controlled trial	High, if no limitation
		Moderate, if some limitations
		Low, if serious limitations
Class B:	[observational]	
	Cohort study	High, if well done with large effect
		Moderate, if well done with effect
		Low, most studies
Class C:	[observational]	
	Non-randomized trial with concurrent or historical controls	
	Case-control study	Low
	Population-based descriptive study	Low
	Study of sensitivity and specificity of a diagnostic test	Low*
*Following individual study review, may be elevated to Moderate or High depending upon study design.		
Class D:	[observational]	

Design of Study Current ICSI System		ICSI GRADE System
	Cross-sectional study	Low
	Case series	
	Case report	
Class M:	Meta-analysis	Meta-analysis
	Systematic review	Systematic review
	Decision analysis	Decision analysis
	Cost-effectiveness analysis	Cost-effectiveness analysis
Class R:	Consensus statement	Low
	Consensus report	Low
	Narrative review	Low
	Guideline	Guideline
Class X:	Medical opinion	Low
Class Not Assignable		Reference

Evidence Definitions

High Quality Evidence = Further research is very unlikely to change confidence in the estimate of effect.

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Low Quality Evidence = Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain.

In addition to evidence that is graded and used to formulate recommendations, additional pieces of literature will be used to inform the reader of other topics of interest. This literature is not given an evidence grade and is instead identified as a Reference throughout the document.

Clinical Algorithm(s)

A detailed and annotated clinical algorithm for immunization administration is provided in the original guideline document .

Scope

Disease/Condition(s)

- Diphtheria
- Tetanus
- Pertussis
- *Haemophilus influenza b* (Hib) infection
- Hepatitis A (Hep A)
- Hepatitis B (Hep B)
- Herpes zoster/shingles

- Human papillomavirus (HPV) infection
- Poliomyelitis
- Influenza
- Measles
- Mumps
- Rubella
- Meningococcal infection
- Pneumococcal disease
- Rotavirus infection
- Varicella

Guideline Category

Prevention

Clinical Specialty

Family Practice

Geriatrics

Infectious Diseases

Internal Medicine

Nursing

Pediatrics

Preventive Medicine

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Health Plans

Hospitals

Nurses

Pharmacists

Physician Assistants

Physicians

Public Health Departments

Guideline Objective(s)

- To increase the percentage of patients who are up-to-date with recommended immunizations
- To increase the percentage of patients/parents who receive education regarding immunizations

Target Population

Persons of all ages in the United States

Interventions and Practices Considered

1. Routinely recommended vaccines:
    - Hepatitis B (Hep B)
    - Diphtheria and tetanus toxoids with acellular pertussis (DTaP); tetanus-diphtheria-acellular pertussis vaccine (Tdap)
    - *Haemophilus influenzae* type b (Hib)
    - Inactivated poliovirus (IPV)
    - Pneumococcal conjugate (PCV) and pneumococcal polysaccharide (PPSV)-1 and PPSV-2
    - Measles, mumps, rubella (MMR) or combined measles, mumps, rubella and varicella vaccine (MMRV)
    - Varicella
    - Hepatitis A (Hep A) vaccine
    - Influenza vaccine (trivalent inactivated influenza vaccine [TIV] and live, attenuated influenza vaccine [LAIV])
    - Meningococcal conjugate vaccine (MCV4)
    - Meningococcal polysaccharide vaccine (MPSV4)
    - Human papillomavirus (HPV)
    - Rotavirus vaccine
    - Herpes zoster/shingles vaccine
2. Patient/parent education
3. Recording of adverse events
4. Development of systems to track the immunization status of patients

Major Outcomes Considered

- Antibody responses
- Incidence of disease or illness
- Safety and protective efficacy of vaccinations
- Cost-effectiveness of vaccinations
- Adverse effects of vaccinations

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A consistent and defined process is used for literature search and review for the development and revision of Institute for Clinical Systems Improvement (ICSI) guidelines. The literature search was divided into two stages to identify systematic reviews (stage I) and randomized controlled trials, meta-analyses and other literature (stage II). Literature search terms used for this revision are below and include literature from October 1, 2010, through December 31, 2011.

Search terms included: diphtheria, tetanus; pertussis; hepatitis A and B; rotavirus; meningococcal, pneumococcal, inactivated polio virus, herpes zoster, human papillomavirus; influenza; measles, mumps, rubella; varicella; haemophilus influenzae B. The Cochrane and PubMed databases were searched. The search was limited to systematic reviews and randomized control trials.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Following a review of several evidence rating and recommendation writing systems, Institute for Clinical System Improvement (ICSI) has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

Crosswalk between ICSI Evidence Grading System and GRADE

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	Case-control study	Low
	Population-based descriptive study	Low
	Study of sensitivity and specificity of a diagnostic test	Low*
*Following individual study review, may be elevated to Moderate or High depending upon study design.		
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	Case series	
	Case report	
Class M:	Meta-analysis	Meta-analysis
	Systematic review	Systematic review
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In addition to evidence that is graded and used to formulate recommendations, additional pieces of literature will be used to inform the reader of other topics of interest. This literature is not given an evidence grade and is instead identified as a Reference throughout the document.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Guideline Development Process

A work group consisting of 6 to 12 members that includes physicians, nurses, pharmacists, and other healthcare professionals relevant to the topic, along with an Institute for Clinical Systems Improvement (ICSI) staff facilitator, develops each document. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2 members may be recruited from medical groups or hospitals outside of ICSI.

The work group will meet for 7 to 8 three-hour meetings to develop the guideline. A literature search and review is performed and the work group members, under the coordination of the ICSI staff facilitator, develop the algorithm and write the annotations and literature citations.

Once the final draft copy of the guideline is developed, the guideline goes to the ICSI members for critical review.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Cost-Effectiveness of Varicella Vaccine

It is cost effective to do immune status testing for all persons 13 years of age and older, who believe they are nonimmune, before vaccinating against varicella. More than 75% of them will be immune. The prevaccination testing will also substantially reduce the average number of needle sticks that patients in this age range need. For most that number will be only one.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Critical Review Process

Every newly developed guideline or a guideline with significant change is sent to Institute for Clinical Systems Improvement (ICSI) members for Critical Review. The purpose of critical review is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the guideline. Critical review also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes necessary across systems in their organization to implement the guideline.

All member organizations are expected to respond to critical review guidelines. Critical review of guidelines is a criterion for continued membership within ICSI.

After the critical review period, the guideline work group reconvenes to review the comments and make changes, as appropriate. The work group prepares a written response to all comments.

Approval

Each guideline, order set, and protocol is approved by the appropriate steering committee. There is a steering committee for Respiratory, Cardiovascular, Women's Health, and Preventive Services. The Committee for Evidence-based Practice approves guidelines, order sets, and protocols not associated with a particular category. The steering committees review and approve each guideline based on the following:

- Member comments have been addressed reasonably.
- There is consensus among all ICSI member organizations on the content of the document.
- Within the knowledge of the reviewer, the scientific recommendations within the document are current.
- When evidence for a particular recommendation in the guideline has not been well established, the work group identifies consensus statements that were developed based on community standard of practice and work group expert opinion.
- Either a critical review by members has been carried out, or within the knowledge of the reviewer, the changes proposed are sufficiently familiar and sufficiently agreed upon by the users that a new round of review is not needed.

Once the guideline, order set, or protocol has been approved, it is posted on the ICSI Web site and released to members for use.

Revision Process of Existing Guidelines

ICSI scientific documents are revised every 12 to 36 months as indicated by changes in clinical practice and literature. ICSI checks with every work group 6 months before the schedule revision to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

ICSI staff working with the work group to identify any pertinent clinical trials, meta-analysis, systematic reviews, or regulatory statements and other professional guidelines conduct a literature search. The work group will meet for 1-2 three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

A second review by members is indicated if there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations. If a review by members is not needed, the document goes to the appropriate steering committee for approval according to the criteria outlined above.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is classified for selected recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate and timely administration of vaccines

Potential Harms

- Adverse effects (i.e., local reactions, fever, mild forms of disease with attenuated formulations) specific to vaccines
- Meningococcal vaccine given alone or with tetanus and diphtheria (Td) has rates of 55% to 59% systemic effects and 4% to 5% severe (prevention of functions of daily living) adverse events. The most common adverse events are transient and mild and include headache, fever and local injection pain. In randomized, double-blinded trials, the rates of severe adverse events are similar to placebo injections.
- Postlicensure studies of measles, mumps, rubella, and varicella (MMRV) suggest an increased risk of febrile convulsions 7 to 10 days post-vaccination in children aged 12 to 23 months who received MMRV vaccine compared to children who received measles, mumps, rubella (MMR) and varicella separately at the same time. It is estimated that one additional febrile convulsion would occur in every 2,300 children vaccinated with MMRV compared to children who received MMR and varicella concurrently and in separate injections.
- The two-dose schedule of hepatitis B vaccine increases the operational complexity for immunization administration in a clinic serving multiple ages of children and can therefore increase resultant risk of error.
- Numerous instances of syncope, sometimes with significant injury from falling, have been reported with human papillomavirus (HPV) vaccine. More than half occurred within 5 minutes of receipt of the vaccine and 70% within 15 minutes. The Advisory Committee on Immunization Practice is recommending patients being given human papillomavirus should wait in the room in a sitting or reclining position for 15 minutes.
- The effect on safety and efficacy of live attenuated influenza vaccine co-administration with influenza antiviral medications has not been studied. However, because influenza antivirals reduce replication of influenza viruses, live attenuated influenza vaccine should not be administered within 48 hours after cessation of influenza antiviral therapy, and influenza antiviral medications should not be administered for 2 weeks after receipt of live attenuated influenza vaccine.
- Temporary vaccine precautions – two conditions are temporary precautions to vaccination:
    - Moderate or severe acute illness (all vaccines)
    - Recent receipt of an antibody-containing blood product (applies only to MMR and varicella-containing vaccines; does not apply to herpes zoster vaccine)

See also Appendix A, "Guide to Contraindications and Precautions to Commonly Used Vaccines," in the original guideline document for more information.

Contraindications

Contraindications

- Permanent vaccine contraindications – only two conditions are generally considered to be permanent:

    - Severe (anaphylactic) allergic reaction to a vaccine component or following a prior dose of a vaccine
    - Encephalopathy not due to another identifiable cause occurring within seven days of pertussis vaccination
- Temporary vaccine contraindications – two conditions are temporary contraindications to vaccination with live vaccines:
    - Pregnancy
    - Immunosuppression
- Pregnancy is an absolute contraindication to varicella vaccination.
- Use of certain immunosuppressant medications may be a contraindication to administration of certain vaccines, particularly live viral vaccines. As a general rule, avoid administering live viral vaccines (rotavirus; measles, mumps and rubella vaccine [MMR]; varicella; zoster; live, attenuated influenza vaccine [LAIV]) to persons receiving the following medications (or dosage of medication listed):
    - Corticosteroids
    - Chemotherapy or radiation
    - Methotrexate
    - Azathioprine
    - 6-Mercaptopurine
    - Tumor necrosis factor inhibitors (adalimumab, etanercept, infliximab, etc.)
    - Other immune modulators
- MMR vaccination should not occur during pregnancy.
- Normal siblings of immunocompromised children should not receive live oral polio vaccine.
- Zoster vaccine (live) should not be administered to:
    - Persons with a history of anaphylaxis/anaphylactoid reaction to gelatin or neomycin
    - Persons with leukemia, lymphomas or other malignant neoplasms affecting the bone marrow or lymphatic system. (However, patients whose leukemia is in remission and who have not received chemotherapy [e.g., alkylating drugs or anti-metabolites] or radiation for at least 3 months can receive zoster vaccine.)
    - Persons with acquired immunodeficiency syndrome (AIDS) or other clinical manifestations of infection with human immunodeficiency viruses including persons with CD4+ T-lymphocyte values less than 200 per mm^3 or less than 15% of total lymphocytes
    - Persons with clinical or laboratory evidence of other unspecified cellular immunodeficiency. (However, persons with impaired humoral immunity [e.g., hypogammaglobulinemia or dysgammaglobulinemia] can receive zoster vaccine.)
    - Persons undergoing hematopoietic stem cell transplantation (HSCT)
    - Persons receiving immunosuppressant medications
    - Persons with active untreated tuberculosis
    - Persons who are or may be pregnant
- Zostavax® should not be administered to pregnant females; furthermore, pregnancy should be avoided for 3 months following vaccination, per manufacturer recommendations.
- Zostavax® should not be used in children, per manufacturer recommendations.
- Contraindications to influenza vaccines include severe allergic reaction to any component of the vaccine, including egg protein, or after previous dose of any influenza vaccine.
- Persons should not receive live attenuated influenza vaccine if they:
    - Have chronic heart disease (except hypertension)
    - Have chronic lung disease (including asthma and reactive airway disease)
    - Have diabetes
    - Have kidney failure
    - Have illnesses that weaken the immune system
    - Are taking medications that weaken the immune system
    - Are children or adolescents receiving aspirin therapy
    - Are pregnant
    - Have a history of allergy to eggs (or any vaccine component)
- Live, attenuated influenza vaccine should not be administered within 48 hours after cessation of influenza antiviral therapy, and influenza antiviral medications should not be administered for two weeks after receipt of live, attenuated influenza vaccine.
- Severe combined immunodeficiency disease (SCID) and intussusception is a contraindication to rotavirus vaccines RotaTeq® and Rotarix®.

See original guideline document and Appendix A, "Guide to Contraindications and Precautions to Commonly Used Vaccines," for more information. See also http://www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm.

Qualifying Statements

Qualifying Statements

- Vaccine shortages continue to occur in the United States and are the result of a number of factors including companies leaving the vaccine market, manufacturing or production problems, unexpected demand for new vaccines or to changes in vaccine recommendations. On occasion, shortages necessitate temporary changes in recommendations for their use. Information about the shortages including projected duration and recommendations for temporary changes in the immunization schedule are provided by the Advisory Committee on Immunization Practices (ACIP). The work group recommends that all practitioners be kept abreast of the latest national information on vaccine shortage available at the Centers for Disease Control and Prevention (CDC) Web site at http://www.cdc.gov/vaccines/vac-gen/shortages/default.htm .
- Vaccines administered outside the United States can generally be accepted as valid if the schedule was similar to that recommended in the United States (i.e., minimum ages and intervals). Only written documentation should be accepted as evidence of previous vaccination. Written records are more likely to predict protection if the vaccines, dates of administration, intervals between doses, and the person's age at the time of vaccination are comparable to United States recommendations. If a question exists about whether vaccines administered outside the United States were immunogenic, repeating the vaccinations is usually safe and avoids the need to obtain and interpret serologic tests. If avoiding unnecessary injections is desired, serologic testing might be helpful in determining which vaccinations are needed.
- The ACIP, the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP) state a preference for the use of licensed combination vaccines over separate injection of their equivalent component vaccines. The one exception is measles, mumps, rubella, and varicella (MMRV) administered as dose one at age 12 through 47 months. See Annotation #18 "Measles, Mumps and Rubella/Measles, Mumps, Rubella and Varicella (MMR/MMRV) Vaccine" in the original guideline document for information related to febrile seizures.
- The information contained in this Institute for Clinical Systems Improvement (ICSI) Health Care Guideline is intended primarily for health professionals and other expert audiences.
- This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in their individual case.
- This ICSI Health Care Guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.
- The Immunization work group realizes that the CDC updates immunization recommendations in January, July, and October. The CDC's Web site http://www.cdc.gov/vaccines/ provides the most current schedule.

Implementation of the Guideline

Description of Implementation Strategy

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Implementation Recommendation

Prior to implementation, it is important to consider current organizational infrastructure that address the following:

- System and process design
- Training and education
- Culture and the need to shift values, beliefs and behaviors of the organization.

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

- Develop tracking systems in order to establish immunization status of patients under the provider's care, with the capability to produce reminders and recalls for immunizations that are due and/or not on time. (*Annotation #8*)
    - Develop a plan for periodic medical record audits, paper medical record or electronic health records in order to track outcomes and identify barriers.
- Remove barriers to immunization services. (*Annotation #3*)
- Develop system-based protocols to include specific criteria around immunizations that may be due at the current visit, or those immunizations not on time, including a statement indicating immunization(s) may be given at any time during the visit (based on specific criteria).
    - Provide staff training and education around routine standing orders.
    - Make it clear to staff that routine standing orders are clinician orders that allow for administration of immunizations (those due or not on time).
    - Clearly define those staff who may administer these immunizations (registered nurse [RN], licensed practical nurse [LPN], certified medical assistant [CMA], etc.).
- Develop education for providers and staff around patients at risk/high risk who require adjustments or have contradictions to specific (required) immunizations.
    - Develop criteria and alerts for tracking these patients.
    - Develop criteria in paper medical record or electronic health records for documentation of patients at risk/high risk.
- Develop a means for communicating vaccine shortages to practitioners, as well as providing updates on status of shortages. This information is available on the Centers for Disease Control and Prevention Web site .
- Patient Safety: Provide education to clinicians and staff around risk factors and immunizations in all age groups. Stress the importance of reviewing this guideline and/or any of the resources listed (in this guideline) as a reference.
- Develop a system to ensure immunization information is being tracked in state or local registries. (*Annotation #6*)

Implementation Tools

Clinical Algorithm

Quality Measures

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Related NQMC Measures

Immunizations: percentage of patients who by age 13 years were up-to-date with the following recommended adolescent immunizations: one human papillomavirus vaccine (HPV) (for females), one meningococcal (MCV4), one tetanus, diphtheria toxoids and acellular pertussis vaccine (Tdap), and one influenza within the last year.

Immunizations: percentage of adult patients, 19 years and older, who are up-to-date with the following immunizations: one tetanus, diphtheria toxoids vaccine (Td) in the last 10 years, two doses of varicella or history of disease up to year 1995, pneumococcal polysaccharide vaccine (PPSV23) for patients 65 years and older, one influenza within the last year, and herpes zoster/shingles for patients 60 years and older.

Immunizations: percentage of patients or parents (if patient younger than 18 years) who receive education regarding the importance of immunizations and recommended immunization schedules.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

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Guideline Developer(s)

Institute for Clinical Systems Improvement - Nonprofit Organization

Guideline Developer Comment

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Guideline Committee

Immunizations Work Group

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Availability of Companion Documents

The following is available:

- Immunizations. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement; 2012 Mar. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site .

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org ; e-mail: icsi.info@icsi.org.

Patient Resources

None available

NGC Status

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